Synopsis

Ph.D. in Food Service Management and Dietetics

Bone Health and Risk Assessment of Menopausal Women for Osteoporosis and Strategic Diet Care Practices using Calcite Enriched Recipes

Investigator

Kalaipriya.S

(Reg No:18PHFDF001)

Supervisor

Dr.R.Radha

Assistant Professor (SG)

Department of Food Service Management and Dietetics

Submitted to

Avinashilingam Institute for Home Science and Higher Education for Women

Coimbatore

January 2022

Introduction

Osteoporosis is a disease characterized by low bone mineral density where bone becomes weak and brittle. Osteoporosis is becoming a public health problem in India due to lower normative index of Bone Mineral Density (BMD) as compared to western countries. It is reported that 42.5% women and 24.6% men above the age of 50 years suffer from osteoporosis in India (Kadam *et al.*,2018). After women are past their menopausal stage, both onset and progression of osteoporosis gets accelerated due to deficiency of estrogen. Also inadequate intake of calcium, lack of physical activity,vitamin D deficiency and lack of awareness on osteoporosis appear to play a vital role in making women prone to osteoporosis. Eggshell powder is a natural source of calcium. Clinical studies in postmenopausal women and women with senile osteoporosis showed that eggshell powder reduces joint pain. Considering all the above facts, the present study was carried to assess the risk of osteoporosis and to impart awareness through the formulation and development of calcite based recipes.

The Objectives of the Study Includes

- To assess the risk factors associated with osteoporosis among selected adult women
- To formulate egg shell calcite powder and determine its characteristics
- To develop calcite incorporated recipes
- To create awareness on calcite and its role in the prevention and management of osteoporosis

Methodology

The study was carried out through three phases as:

Phase I **:** Collection of data on demographic profile, anthropometric measurements, physical activity , exposure to sunlight and dietary assessment

Phase II **:** Association of risk factors of osteoporosis among selected subjects

Phase III **:** Development of calcite (egg shell) incorporated recipes and promoting bone health through awareness

Phase I : Collection of Data on Demographic Profile, Anthropometric Measurements, Physical Activity, Exposure to Sunlight and Dietary Assessment

Selection of Study Area:

Based on easy accessibility and availability of women subjects, the investigator chose areas in and around Coimbatore and Tiruppur districts (Tamil Nadu) as the areas of study.

Selection of Sample:

One thousand thirty six women in the age group of 40 to 60 years at various stages of menopause were selected for the study. Menopausal stage includes peri menopause, menopause and post menopause. Perimenopause begins about eight to 10 years before menopause. Menopause is a period were women experience no menstrual periods for a year and post menopause is when women experiences more than one year of no menstrual periods (WHO,1996) (Cleveland,2021).

Sample Size Determination:

Sample size was determined using the formula by Gayathri, 2017. The samples were selected using purposive random sampling methodand considering inclusion and exclusion criteria mentioned below.

Inclusion Criteria:

- Female subjects of age above 40 years.
- Those who are willing to participate in the study.

Exclusion Criteria:

- Without any chronic illness and disabilities
- Under regular calcium supplementation

The study was approved by the Institutional Human Ethical Committee (IHEC) of Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore. A well-structured interview schedule was developed to collect data on demographic profile, physical activity, exposure to sunlight, menopausal stage and symptoms, diet pattern, family history and self history of the selected subjects.

Demographic Data:

Demographic data including age, religion, marital status, education, occupation and monthly income were collected. The socio economic data was collected and categorised based on Modified Kuppuswamy scale (Wani,2019).

Physical Activity and Sun Exposure:

The sun exposure pattern (Harinarayan,2018) and physical activity of subjects were collected based on International Physical Activity Questionnaire (IPAQ) (Forde,2018).

Menopausal Symptoms:

The most common symptoms of menopause are joint and muscular discomfort, physical and mental exhaustion, sleeping problems, hot flashes, sweating, irritability, dryness of vagina, anxiety, depressive mood, sexual problems, heart discomfortand bladder discomfort (Nanette,2015) (Harvard,2017) (NHS,2018). Data on the type of symptoms experienced by the selected subjects were collected and analysed.

Diet Pattern:

There is no single method available which would be suitable enough to gather all the information regarding diet pattern. Thus a combination of various methods were used in the present study. Food frequency questionnaire, diet diversity and 24 hour dietary recall methods were used to obtain data on diet pattern of the selected subjects.

Food Frequency Questionnaire (FFQ):

The food frequency questionnaire was formulated to gather qualitative information on the frequency of the consumption of various calcium rich food items covered under major food groups.

24 hour Dietary Recall Method:

The subjects were asked to recall and report details of all the food items and beverages that they had consumed in the previous day (last 24 hours) and also the respective ingredients were recorded according to serving sizes. Nutrients consumed per each meal were calculated and compared with the Recommended Dietary Allowances (RDA) by ICMR,2010.

Diet Diversity:

The present study was aimed at collecting the diet diversity of the subjects under the following food groups i]Cereals ii]White roots and tubers, iii]Vitamin A-rich vegetables and tubers, iv]Dark green leafy vegetables, v]Other vegetables, vi]Vitamin A-rich fruits, vii]Other

fruits, viii]Organ meat, ix]Flesh meats, x]Eggs, xi]Fish & seafood, xii] Legumes, nuts & seeds, xiii] Milk & milk product , xiv]Oils & fats, xv]Sweets ,xvi]Spices, condiments, beverages etc (Srinivasalu *et al.*, 2017).

Osteoporosis Risk Assessment:

In the present study three tools were used to assess the osteoporosis risk among selected adult women. The three tools were Osteoporosis Self assessment Tool (OST), Osteoporosis Risk Assessment Instrument (ORAI) and Simple Calculated Osteoporosis Risk Estimation (SCORE).

Anthropometric Measurements:

Anthropometric measurements like height, weight were recorded and Body Mass Index was calculated

Family History and Self History:

Apart from the data discussed above, family history and self history of the subjects were collected. Common morbidities like obesity, diabetes, high or low blood pressure, CVD, thyroid dysfunction, epilepsy and osteoporosis were included and the history of subject's family members were also collected. Based on the data collected, the morbidities of the selected subjects were identified.

Pilot Study:

A pilot study was conducted among 60 selected subjects with the same inclusion and exclusion criteria to validate the interview schedule and osteoporosis risk assessment tool.The Bone Mineral Density (BMD) was assessed using bone densitometry for the selected subjects. The three osteoporosis risk assessment tools like OST (Osteoporosis Self Assessment Tool), ORAI (Osteoporosis Risk Assessment Instrument) and SCORE (Simple Calculated Osteoporosis Risk Estimation) were used and compared statistically with actual BMD of the selected subjects. Finally the ambiguous questions were eliminated from the interview schedule.

Collection of Data:

After orienting the subjects about the purpose and modality of the study, their consent was obtained and subsequently data was collected using the interview schedule.Questions were explained in detail using the regional language for their better understanding and their

responses were noted down carefully. If there were any vague answers by subjects, the concept were explained again and their responses were recorded accurately one more time.

Phase II: Association of Risk Factors of Osteoporosis among Selected Subjects

In phase II risk factors of osteoporosis like calcium intake, physical activity, sun exposure, Body Mass Index (BMI), knowledge on osteoporosis were assessed. The selected subjects were categorised based on age group into 40 to 45 years, 46 to 50 years, 51 to 55 years and 56 to 60 years. Risk factors were assessed and compared statistically with at risk subjects.

Bone Mineral Density (BMD) screening:

About 416 sub samples were selected based on the inclusion criteria to perform Bone Mineral Density (BMD) screening using bone densitometry.

Inclusion Criteria:

- Subjects willing for BMD assessment
- Subjects willing to participate in awareness session
- Subjects having smart phone

Analysis of Data:

Data collected from the interview schedule was coded and was analysed using SPSS 21 (Statistical Package for Social Sciences).

Phase III: Development of Calcite (egg shell) Incorporated Recipes and Promoting Bone Health through Awareness

Development of Egg Shell Calcite Powder:

Collection of Egg Shells:

The chicken egg shells were collected from the egg product development industry, from the same batch of white leghorn hen. The underlying condition was that the hens were uniformly fed. The collected egg shells were washed properly and then dried .The egg shells were then powdered and stored in air tight container.

Processing of Egg Shell Powder:

The egg shell powder was washed thoroughly using purified water (less than 10 ppm) to ensure the removal of egg shell membrane and other impurities if any.

Development of Egg Shell Calcite Powder:

The powdered and washed egg shell was heated in muffle furnace at 900^{o}C at half an hour interval of every 200^{o} raise in temperature. Egg shell powder was maintained at 900^{o}C for four hours and the final sample was taken out.

Characterization of Developed Egg Shell Powder:

Characteristics like size, shape, nature of developed egg shell powder, ash, moisture and calcium content were analysed using various methods like FESEM (Field Emission Scanning Electron Microscope), heavy metal analysis, XRD (X-Ray Diffraction) and FTIR (Fourier Transform Infrared Spectroscopy). After formulation and characterisation of calcite powder, the calcite incorporated recipes were developed.

Development of Recipes

Selection of Ingredients:

Recipes were developed with ingredients that are rich in protein, calcium, omega 3 fatty acid and phytoestrogens.

Development of Recipes:

Recipes were developed based on starter, main course, dessert, snacks and ready to eat products. Ten recipes were developed under each category. Totally 50 recipes were prepared by incorporating the developed calcite powder in three variations as 250mg, 350mg, 450mg (Trailokya *et al.,* 2017).

Recipes like Garlic soup, Horse gram dhal (*Macrotylomauniflorum*) soup, Agathi leaves (*Sesbania grandiflora*) soup, Soya chunks kebab,thoothuvalai (*Solanum procumbens*) soup, vallarai (*Centellaasiatica*) soup, Egg fingers, Modakathan (*Green cardiospermumhalicacabum*) soup, Greengram dhal sprouts salad, Strawberry cucumber salad were prepared under thestarter category.

Spanish omelette, Mughlai paratha, Cabbage ragi (finger millet) adai, Wheat garlic pasta, Ragi (finger millet) rotti, Methi (fenugreek leaves) pulav, Amaranth (Amaranthus) leaves dosa, Mint rice, Manathakkali leaves (*Solanum nigrum*) rice, Bajra (pearl millet) kichdi were prepared undermaincourse.

With respect to desserts, Dates and almond brownie, Carrot kheer, Almond rabdi, Fruit custard, Fig ladoo, Sweet yogurt, Ragi (finger millet) semolina payasam, Shrikhand, Banana honey dessert, Sweet bajra porridge were prepared.

Egg patties, Flaxseed ladoo, Multigrain bread paneer, Soyabean vada, Groundnut chikki, Kothimbir vadi, Paneer cutlet, Sesame seed balls, Ragi (finger millet)banana pancake, Wheat flour appam under the snacks category.

Ready to Eat Products that were developed includes Drumstick (*Moringa oleifera*) leavespodi, Curry leaves podi, Groundnut chutney podi, Garlic podi, Thoor dhal podi, Sesame seed podi, Horse gram dhal (*Macrotyloma uniflorum*) podi, Sundaikkai vathal (*Solanum torvum*) podi, Amla (*Phyllanthus emblica*) murabba and Pumpkin seeds podi.

Sensory Evaluation:

The developed recipes were evaluated by semi trained panel (15 members) with the help of 9 point hedonic scale for its reliability, validity and discriminative ability.The sensory evaluation scores were analysed statistically and the nutritive value of each recipe was calculated using Indian Food Composition Tables, 2017.

Creating Awareness on Calcite and its Role in the Prevention and Management of Osteoporosis

Pre- awareness Knowledge Assessment on Osteoporosis and Bone Health:

To carry out pre awareness knowledge, Osteoporosis Knowledge Assessment Tool (OKAT) (Senthilraja *et al.,* 2019) was used. OKAT is a reliable and frequently used tool to assess knowledge about osteoporosis. OKAT tool consisted of 20 questions. Correct answers were awarded one point and wrong answers were not awardedany point. The total score of the participant was computed and categorized.

Development of Awareness Material:

After the initial assessment of knowledge of the subjects, awareness material containing information on osteoporosis, role of calcite in the prevention and management of osteoporosis, egg shell calcite powder incorporated recipes,causes and risk factors of osteoporosis and its prevention was prepared.

Conduct of Awareness Session:

Awareness sessions were conducted for the selected subjects in different groups based on their locale. The sessions were interactive in nature. After the session, the participants were provided soft-copy of the awareness material and e-booklet on calcite incorporated recipes for their future use.

Post- awareness Knowledge Assessment:

After the awareness session,the same OKAT Tool was sent to the subjects for assessing their knowledge on osteoporosis and bone health. After receiving the answers, scoring was done based on the same criteria as pre-awareness knowledge assessment.Then pre awareness and post awareness knowledge on osteoporosis was compared and the effectiveness of awareness was assessed.

Salient Findings of the Study are Summarized below:

Phase I: Collection of Data on Demographic Profile, Anthropometric Measurements,Physical Activity, Exposure to Sunlight and Diet Pattern

- Among the selected 1036 subjects, 434 were in the age group of 40-45 years, 373 subjects were between 46-50 years,111 subjects were in the range of 51-60 years and 118 subjects were between 56-60 years.
- Among the selected subjects 72% belonged to nuclear family, 23% of them were living as a joint family and 5% were from extended family.
- Regarding the educational qualification of the subjects, 60% had completed middle and high school. 22% of the subjects were either graduates or post graduates, about 12% had completed primary school, 4% of them had a diploma and only 2% of the subjects were professional degree holders.
- Socio economic status reveals that twenty nine percent of the subjects belonged to upper middle class. About 28% belonged to upper lower, 26% of them were in the lower middle category, 9% of subjects belonged to lower sectionand only 8% of subjects were from upper class family.
- From the selected subjects, 544 were employed, 428 subjects were unemployed and 64 subjects were entrepreneurs.
- Four ninety-six subjects were under peri-menopausal stage followed by 286 subjects at menopausal stage and remaining 254 subjects were past their menopausal stage.
- A pilot study on 60 subjects was conducted using 3 tools namely ORAI (Osteoporosis Risk Assessment Instrument), OST (Osteoporosis Self assessment Tool) and SCORE (Simple Calculated Osteoporosis Risk Estimation). Further Bone Mineral Density (BMD) was measured directly using bone densitometry. The values obtained from the 3 tools were compared to the BMD measured directly. It was found that the results of the ORAI tool and the actual BMD were the closest.Hence ORAI was selected to carry out further study.

- According to the osteoporosis risk assessment done using ORAI tool among selected subjects, 65% of the subjects were found to be at risk of osteoporosis and only 35% of them were not at risk.
- With respect to the menopausal symptoms faced by the subjects,19 percent of the respondents had irritability, followed by 14 percentage of them who had physical and mental exhaustion, 12 percent of them suffered from hot flushes, sweating, dryness of vagina, anxiety and depressive mood. About 10 percent of the women had sleeping problems and below 5 percent of the women had sexual problems, heart discomfort, bladder discomfort, joint and muscular discomfort.
- Four hundred and eight subjects performed moderate level of physical activity, 248 subjects did high level of physical activity, 380 subjects did moderate physical activity. Data collected revealed 562 subjects had inadequate amount of sunlight exposure and remaining 474 subjects were exposed to sunlight adequately.
- Regarding dietary pattern of selected subjects, 692 subjects were non-vegetarians , 253 subjects were vegetarians and 91 of them were ova vegetarians.
- Calcium intake was calculated using 24 hour diet recall method and the nutritive value was computed using Indian Food Composition Tables. It was found that the majority of subjects consumed less than 800 mg of calcium per day.
- Considering the diet diversity, all of the subjects consumed cereals, pulses, legumes oils and fats. 978 subjects consumed milk and milk products, 723 subjects consumed eggs,534 subjects consumed nuts and seeds and 837 consumed green leafy vegetables.
- Among the family medical history of selected subjects 502 had blood pressure issues, 327 subjects had diabetes, 263 of them were obese, 221 subjects had osteoporosis, 93 of them had thyroid dysfunction, 45 of them had epilepsy and 41 of them had cardiovascular disease.
- Among the self-history disclosed by the subjects, 426 subjects had elevated blood pressure followed by 245 subjects with diabetes and 240 of them had thyroid dysfunction. Further 23 subjects had epilepsy and another 39 subjects had radical hysterectomy.
- Two hundred and eighty eight subjects had normal BMI. Further 285 subjects were overweight, followed by 262 who were underweight and another 203 subjects fell under the obese category.

Phase II: Association of Risk Factors of Osteoporosis among Selected Subjects

- With respect to anthropometric measurement, 75 subjects in the age group of 40-45 had normal BMI. In 46-50 years category, 99 subjects were underweight. Similarly 22 subjects in the age group 50-55 years and 31 subjects in the age group of 56- 60 years were obese.
- One hundred and six subjects in the age group of 40 -45 years, 124 subjects in 46-50 year category and 31 subjects in 51-55 years group consumed 400- 800mg of calcium per day and 38 subjects in 56-60 years age group consumed less than 400 mg of calcium per day.
- Comparing physical activity of at risk subjects, in the age groups of 40-45, 85 subjects performed low and moderate physical activity, 112 subjects in the age group of 46 to 50 years performed moderate physical activity, 29 subjects performed high physical activity in the age group of 51 to 55 years and 43 subjects performed low physical activity in the age group 56 to 60 years.
- In the age group of 40 to 45 years 146 subjects, 177 subjects in 46 to 50 years group, 44 subjects in 51 to 55 years category and 62 subjects in 56 to 60 years group had inadequate exposure to sunlight.
- There is statistically significant difference between age, calcium intake, knowledge level and physical activities ofat risk subjects and there is no statistical significance in relationship between BMI and at Risk subjects. As indicated by the f value, knowledge has the most association with at Risk subjects followed by physical activity then age and subsequently calcium intake and sun exposure.
- Bone mineral density of selected samples with respect to various menopausal stages revealed that 77 subjects at pre menopause stage had normal bone mineral density. 52 women subjects at menopause stage were osteopenic and 50 women at post menopause stage were osteoporotic.
- There was statistically significant relationship between physical activity, sun exposure, knowledge and calcium intake of the respondents and BMD risk of the women.

Phase III: Development of Calcite (egg shell) Incorporated Recipes and Promoting Bone Health through Awareness

- Calcite powder was developed. Then the developed powder was incorporated into several recipes.
- Developed egg shell calcite powder was analyzed for its characteristics.
- It was white in color and the size of calcite was between 81-157 nano meter in size.
- The egg shell powder was roughly crystalline in structure and spherical in shape.
- It was also analysed for the presence of heavy metal like lead, cadmium, mercury and arsenic. The results revealed that all the heavy metals were well below the detectable limit.
- The developed calcite contained 97% of Calcium. Moisture content and ash content were determined. It contained no moisture whereas it had an ash content of 53.93%.
- Fifty recipes were developed based on different course of menu like starter, main dish, dessert, snacks and Ready to Eat Products.10 recipes were developed under each of the above categories. The organoleptic evaluation was done for all the 50 recipes.
- Each of the 50 recipes were prepared in three different variants by altering the quantum of calcite at 250, 350 and 450 grams respectively. There was a significant difference in organoleptic property among all three samples (variants).
- The organoleptic scores of all 10 starter recipes were scored between a minimum of 8.09 to maximum of 8.26. Main dish recipes scored between 7.92 and 8.17. Developed dessert recipes scored between 7.32 and 8.32.All the ready to eat products scored between 7.32 and 8.01 and snacks scored between 7.07 to 8.59.
- For creating awareness in the prevention of osteoporosis, several books, journals and e-resources were referred and were compiled into a easily comprehendible e-booklet.
- Awareness was created and effectiveness of awareness sessions were assessed and recorded.
- The results reveal that majority of the subjects i.e 304 out of 410 scored less than 50% before awareness. Whereas after awareness, the majority of subjects numbering 310 scored above 50%.Only 106 subjects scored below 50% after awareness.
- Statistical analysis of pre and post- knowledge of the respondents shows that they were statistically significant. Knowledge level of the study respondents had increased considerably after awareness compared to the pre-awareness stage.

References

1. Cadarette, S.M., Jaglal, S.B., Kreiger, N., McIsaac, W.J., Darlington, G. A & Tu, J.V (2000). Development and validation of the Osteoporosis Risk Assessment Instrument to facilitate selection of women for bone densitometry. *Canadian Medical Association Journal*, *162* (9), 1289-1294.
2. Cleveland clinic (2021).Perimenopause**.**https://my.clevelandclinic.org/health/diseases/21608-perimenopause.
3. Forde, C. (2018). Scoring the International Physical Activity Questionnaire (IPAQ). *University of Dublin*.
4. Gayathri (2017). *Nursing Research in 21st Century*.Statistical basis of sample size calculation.CBS Publishers and Distributers , 234-246.
5. Harinarayan, C.V (2018). How to treat Vitamin D deficiency in sun-drenched India-guidelines. *Journal of Clinical Science Research,* 7 (3), 131-40.
6. Harvard health publishing (2017). Dealing with symptoms of menopause, https://www.health.harvard.edu/womens-health/dealing-with-the-symptoms-of-meno pause.
7. Kadam, N.S., Chiplonkar, S.A., Khadilkar, A.V & Khadilkar,V.V (2018). Prevalence of osteoporosis in apparently healthy adults above 40 years of age in Pune City, India. *Indian Journal of Endocrinology and Metabolism*, 22 (1), 67.
8. Lydick, E., Cook, K., Turpin, J., Melton, M., Stine, R & Byrnes, C (1998). Development and validation of a simple questionnaire to facilitate identification of women likely to have low bone density. *American Journal of Managed Care,4* (1), 37-48.
9. Rajendran, S., Afari-Sefa, V., Shee, A., Bocher, T., Bekunda, M., & Lukumay, P.J. (2017). Does crop diversity contribute to dietary diversity? Evidence from integration of vegetables into maize-based farming systems. *Agriculture & Food Security*, *6*(1), 1-13.
10. Santoro, N., Epperson, C.N & Mathews, S.B (2015). Menopausal symptoms and their management. *Endocrinology and Metabolism Clinics*, 44 (3), 497-515.
11. Senthilraja, M., Cherian, K.E., Jebasingh, F.K., Kapoor, N., Paul, T.V & Asha, H.S (2019). Osteoporosis knowledge and beliefs among postmenopausal women: A cross-sectional study from a teaching hospital in southern India. *Journal of Family Medicine and Primary Care*, *8* (4), 1374.
12. Subramaniam, S., Ima-Nirwana, S & Chin, K.Y (2018). Performance of osteoporosis self-assessment tool (OST) in predicting osteoporosis-a review. *International Journal of Environmental Research and Public Health*, *15* (7), 1445.
13. Trailokya, A., Srivastava, A., Bhole, M & Zalte, N (2017). Calcium and calcium salts. *Journal of the Association of Physicians of India*, *65* (2), 100-3.
14. Wani, R.T (2019). Socioeconomic status scales-modified Kuppuswamy and Udai Pareekh's scale. *Journal of Family Medicine and Primary Care,* 8 (6), 1846.
15. World Health Organization. (1996). Research on the menopause in the 1990s: report of a WHO scientific group.